DARPA-Funded Research Involving Human Subjects and/or Animals

Guidance for Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR)

DARPA-Funded Human Subjects Research

Definition and Regulations

HUMAN SUBJECTS RESEARCH (HSR) aka HUMAN USE

These protocols apply to all research that meets either of the following criteria:

1) Any research involving an INTERVENTION or an INTERACTION with a living person that would not be occurring under usual circumstances.
2) Any research involving data/information/specimens collected originally from people (broadcast video, web-use logs, surveys, etc.) in which the identity of the subject is known, or the identity may be readily ascertained from the information.

REGULATIONS

- *The Common Rule*

  Title 32, Code of Federal Regulations (CFR) Part 219, "Protection of Human Subjects," current edition
  http://www.dtic.mil/biosys/downloads/32cfr219.pdf

- *DoD Directive 3216.02*

  Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," April 27, 2007
  http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf

Suggested Best Practices

Strongly recommend proposing HSR to be conducted during Phase 2; thereby ensuring enough time to prepare and submit human use approval documentation to the Institutional Review Board (IRB) during Phase 1.

If the awarded performer does not have an IRB, recommend:
1) Teaming with an institution who has an IRB or
2) Using a commercial IRB (see website: http://www.circare.org/info/commercialirb.htm)

Commercial IRB Statistics

- Average Turnaround Time: Unconditional approval and/or decision documents returned in a week from the local IRB.
- Average Costs: Initial IRB Review $900-$2750; Annual Continuing IRB Reviews for duration of HSR $400-$2750. Additional fees may apply depending on extra research sites, investigators, etc.
- DARPA will pay for the costs of using a commercial IRB if included in the proposed budget.

HSR Review Information

In addition to a local IRB approval, a headquarters-level (DoD-level) human subjects regulatory review and approval is required for all research conducted or supported by the DoD.

- The Service component (Army, Navy, Air Force) responsible for managing the award can provide further guidance regarding headquarters-level approvals.
- Confirmation of a current Federal Wide Assurance (FWA), Institutional Review Board (IRB) Approval, and appropriate human subjects protection training provided by the performers is required before headquarters-level approval can be issued.

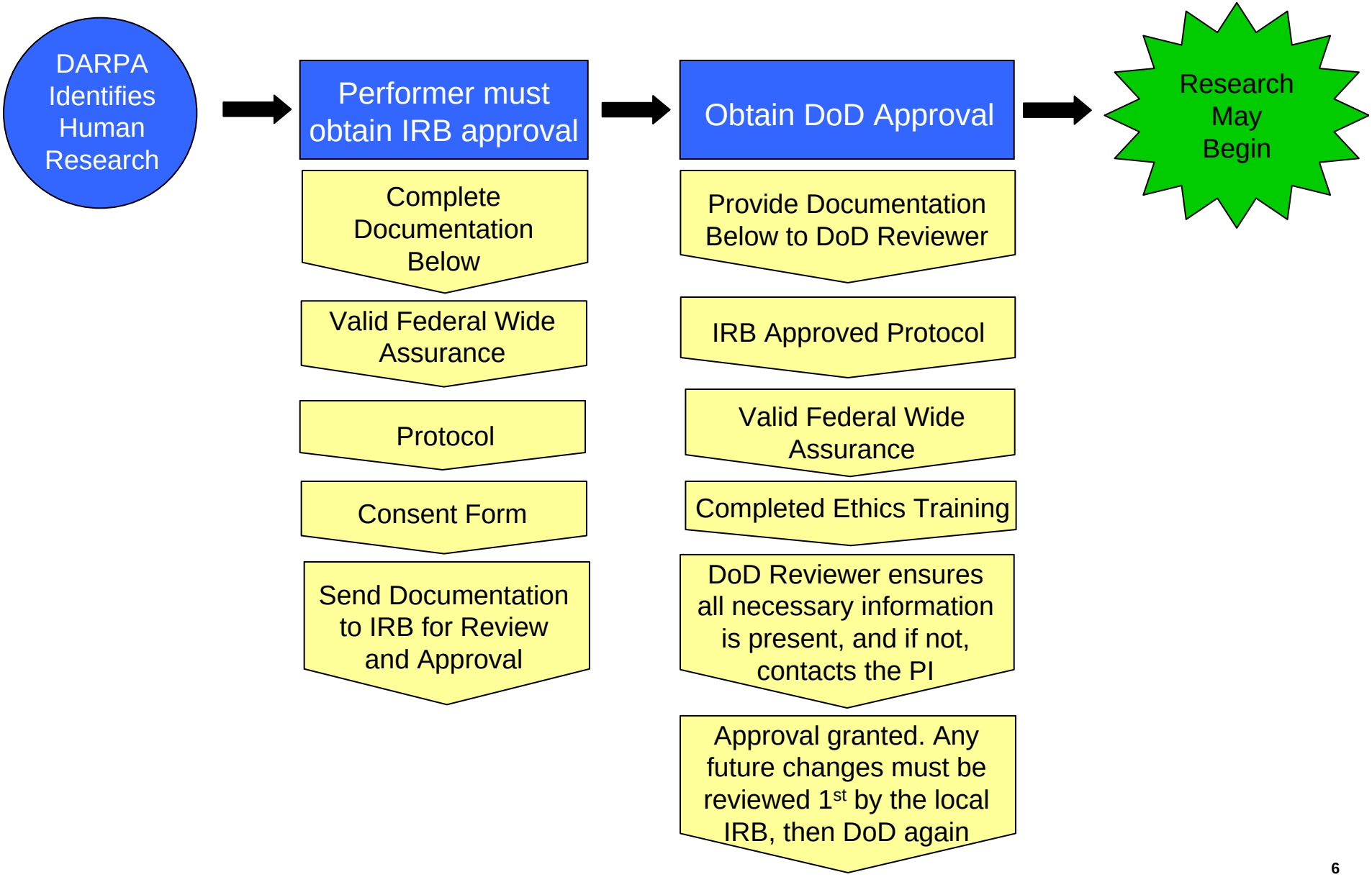
Federal Wide Assurance (FWA) Requirement

- Any performer engaged in HSR must hold a valid FWA through the Department of Health and Human Services. See website: http://www.hhs.gov/ohrp.
- The IRB conducting the review must be named on the Institution's Assurance.

Institutional Review Board (IRB) Requirements

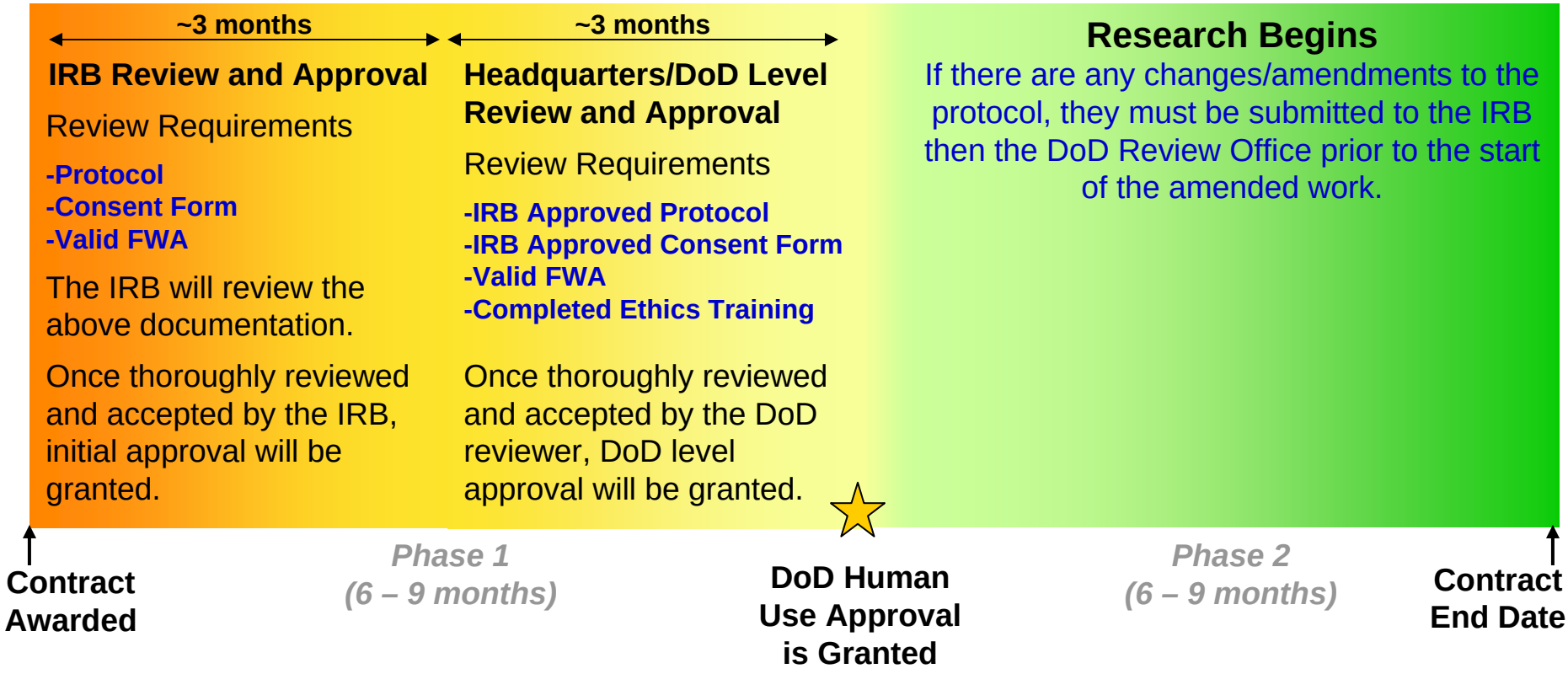
- The **protocol**, separate from the proposal, must include a detailed description of the research plan, study population, risks and benefits of study participation, recruitment, consent process, data collection, and analysis.
- The **consent form**, if applicable to the research, must comply with the Common Rule (32 CFR 219).

Approval Process



The Approval Process and Timeline

PI must submit/complete all items in blue



***Note: Absolutely NO money can be used on human research and testing until DoD approval is granted.**

***Plan for 6-9 months for approval process.**

Definitions

- **Assurance** – A formal written document issued by a federal department ensuring compliance with necessary regulations governing human subject research and describing those proceedings through which compliance will be achieved. Example: Federal Wide Assurance (FWA) through DHHS
- **Common Rule** – The regulation adopted by multiple Federal Agencies for the protection of human subjects in research. The Department of Defense's implementation of the Common Rule is 32 CFR 219.
- **DARPA Agent** – DARPA executes its programs through the Military Departments and other US Government agencies, called Agents, and, where appropriate, demonstrates technical feasibility and defense utility in joint experiments and demonstrations with these Agents. DARPA Agents perform functions such as award and administration of contracts, oversight of technical efforts, and various support functions. In addition, they may actively participate in the development of technology as well as transition opportunities.
- **Informed Consent** – The legally effective written permission and agreement of the human subject or the human subject's legally authorized representative prior to that individual's participation in human subject research. The document should be signed after the individual has been made aware of all foreseeable risks and benefits of participation.
- **Institutional Review Board (IRB)** – A committee designated by an institution to review, approve, and conduct periodic monitoring of research involving human subjects. IRBs assume oversight responsibility for protecting the rights of human subjects.
- **Protocol** – A comprehensive, detailed and specific plan of action for execution of human subjects research. A protocol may include, but is not limited to: objectives, research design, population, recruitment process, data collection, and analyses.

DARPA-Funded Animal Research

Definition and Animal Use Regulations

ANIMAL RESEARCH

The regulations listed below cover research conducted on any "live vertebrate animal that is being used or is intended for use in research, training, or testing, or for experimentation purposes."

Testing on non-living animal tissue or non-vertebrate animals (i.e. shrimp) does not require DoD approval; however, these types of experiments may still require local Institutional Animal Care and Use Committee (IACUC) approval.

REGULATIONS

- *Animal Welfare Regulations and the Animal Welfare Act (AWR and AWA)*
  Title 9, Code of Federal Regulations, Parts 1-4; Title 7, U.S. Code, 2131-2156
  http://www.access.gpo.gov/nara/cfr/waisidx_00/9cfrv1_00.html;
  http://www.nal.usda.gov/awic/legislat/awa.htm
- *The Use of Laboratory Animals in DoD Programs*
  DoD Directive 3216.1
  http://www.dtic.mil/whs/directives/corres/pdf/321601p.pdf
- *The Care and Use of Laboratory Animals in DoD Programs*
  Army Regulation 40-33
  http://www.usapa.army.mil/pdffiles/r40_33.pdf

Steps Toward Animal Research Approval

- Per the Animal Welfare Regulations (AWRs), all research (regardless of the funding source) must be reviewed and approved by the institution's IACUC. These approvals are valid for three years.
- Per the AWRs and AR 40-33, the facilities in which animal research is being conducted must be inspected by the USDA. Maintain the facilities inspection report.

In addition to IACUC approval, ALL efforts involving DoD-funded animal research must undergo a review by a DoD veterinarian as stated in DoDD 3216.1 and AR 40-33. All documentation listed in the previous slide must be reviewed by the DoD veterinarian.

- DoD Veterinary Review Office: Army's Animal Care and Use Review Office (ACURO) at Ft. Detrick
  - USAMRMC Point of Contact: Ms. Nina Cisar
  - Phone: 301-619-6694
  - Email: nina.cisar@amedd.army.mil
- DoD approval is valid for the entire length of the contract, unless there is a major change: change in proposal/SOW, institution, PI, etc.
- The contract can be awarded before approvals are granted with the inclusion of a prohibition clause, stating that performers are NOT allowed to use funds for animal research and testing until approvals are granted.
- New efforts using non-human primates, dogs, cats, and marine mammals require a site visit by a DoD veterinarian. Timing of the site visit is at the discretion of the DoD vet and usually takes place after approval is granted.

Helpful Hints

- Following the award selection process, the performer may contact the DoD Veterinary Review Office POC to begin the approval process.
- The sooner you complete animal use documentation, the sooner your proposal can be approved.
- Information required for DoD animal use review is listed on the check sheet to the right:

DoD Animal use Documentation Checklist

✓ Copy of IACUC-approved protocol and signed approval letter

✓ Copy of all IACUC-approved protocol amendments/modifications, if applicable

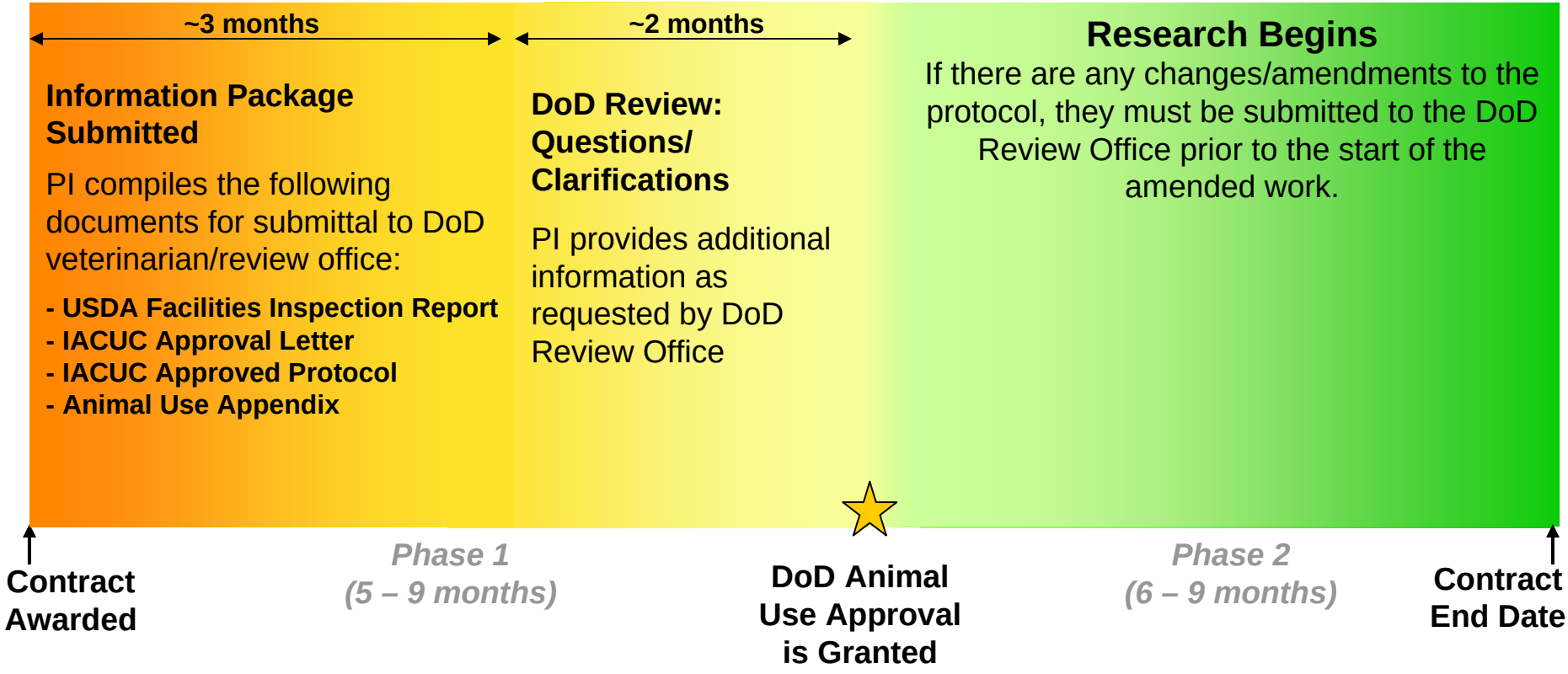
✓ USDA Inspection Report

✓ Institutional accreditations, such as AAALAC (optional)

✓ DoD Veterinary Review Office Animal Use Form (Animal Use Appendix)

✓ Link to Animal Use Appendix: https://mrmc-www.army.mil/animalappendix.asp

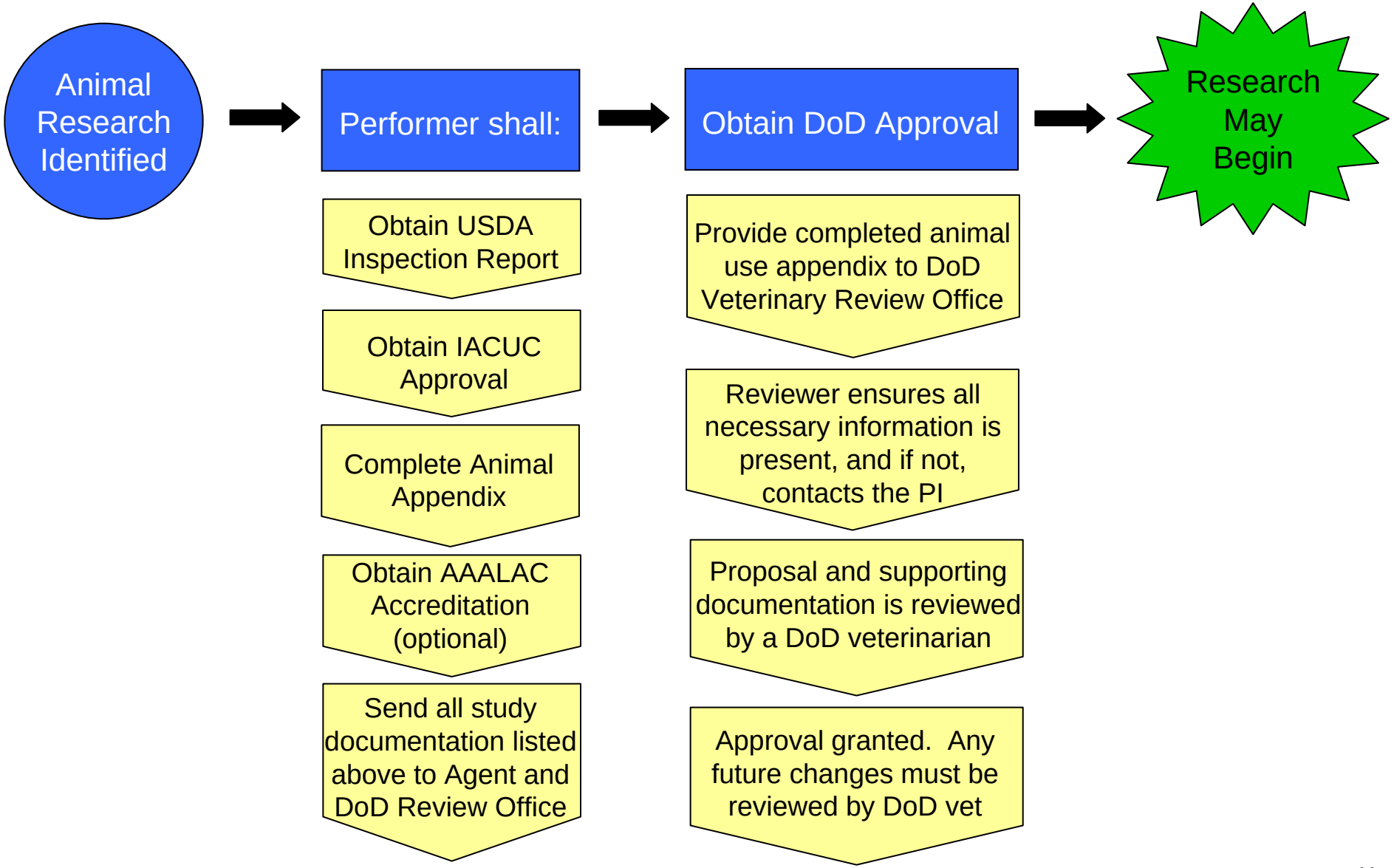
Approval Process Timeline



***Note: Absolutely NO money can be used on animal research and testing (including animal purchase, housing, and care) until DoD approval is granted.**

***Plan for 5-9 months for approval process.**

Approval Process



Definitions

- **Accreditation** – Official Recognition and approval of animal care and use programs and facilities by the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC).
- **Animal** – Any live vertebrate animal that is being used or is intended for use in research, education, training, or testing.
- **Institutional Animal Care and Use Committee (IACUC)** – Committee at the institutional level that oversees and evaluates the institution's animal program, procedures, and facilities to ensure that they are consistent with the regulations and recommendations. May go by other names such as Committee on Animal Care (CAC), Care and Use Committee (CUC), or Animal Care and Use Committee (ACUC).
- **Prohibition Clause** – A clause in a contract forbidding an act or activity. For example, money can be awarded to a performer at the beginning of Phase 1 while they obtain proper approvals; however, per an animal use specific language, the funds cannot be spent on any portion of the project involving animal research until proper approval is granted.
- **Vertebrate** – A member of the subphylum Vertebrata (within the phylum Chordata), specifically, those chordates with backbones or spinal columns.

Questions ?

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